

Ser. No. 09/720,309
Amdt. dated August 27, 2003
Reply to Office action of March 28, 2003

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

Claim 1 (currently amended): A medical device (10) with a proximal end (22) and a distal end (23), an elastomeric bulb (21) at the proximal end for storing fluid under pressure, a fluid acceptor (20) at the distal end and a lumen (12) connecting the bulb and the acceptor for flow of fluid from the bulb to the acceptor when the device is used, and including a control device (25) at the proximal end of the lumen to prevent said flow until said flow is desired

characterised in that

said control device (25) comprises a plug (26) which blocks the lumen at its proximal end and includes a parting line, which enables the plug to be parted into two separate parts, by manual manipulation from outside the lumen, such parting having the effect of opening up fluid communication along the lumen from the elastomeric bulb (21) to the fluid acceptor (20) to fully fill the acceptor, and characterized in that

wherein the plug comprises a co-axial stem (27) and annular part (26) with a diameter at least twice that of the stem, which meet at said parting line wherein the annular part comprises a tapering portion displaying a small end and a large end, the small end being remote from the stem, wherein the annular part comprises a cylindrical portion, wherein the cylindrical portion lies between the tapering portion and the stem, in the axial direction of the plug, wherein the diameter of the cylindrical portion is greater than that of the large end of the tapering portion, including a step between the large end of the tapering portion and the cylindrical portion.

Claim 2 (original): Device as claimed in claim 1 wherein the bulb (21) is coated with a substance to inhibit the passage of the fluid through the wall thickness of the bulb.

Ser. No. 09/720,309
Amdt. dated August 27, 2003
Reply to Office action of March 28, 2003

Claim 3 (original): Device as claimed in claim 2 wherein the coating is on the outside of the bulb wall thickness.

Claim 4 (original): Device as claimed in claim 2 wherein the coating is on the inside surface of the bulb wall.

Claim 5 (original): Device as claimed in claim 1 wherein the plug (26) carries a fluid-tight skirt membrane which extends proximally from the proximal end face of the plug.

Claim 6 (previously presented): Device as claimed in claim 1 wherein the acceptor is a balloon (20).

Claim 7 (previously presented): Device as claimed in claim 1 wherein the medical device is a catheter (10).

Claim 8 (original): Device as claimed in claim 7 wherein the catheter is a drainage catheter.

Claim 9 (withdrawn): A medical device which is a drainage catheter (10) having a proximal end (22) and a distal end (23) and first and second lumens extending therebetween, the first lumen serving as a drainage lumen and having a fluid inflow port at its distal end and a fluid drain coupling at its proximal end, the second lumen serving to convey inflating fluid from a fluid supply element (21) at its proximal end to a fluid acceptor balloon (20) at its distal end, with the fluid supply element (21) and the fluid drain coupling arranged side by side at the proximal end of the lumen
characterised by

Ser. No. 09/720,309
Amdt. dated August 27, 2003
Reply to Office action of March 28, 2003

a sleeve which extends around both the fluid drain coupling and the fluid supply element.

Claim 10 (withdrawn): A device as claimed in claim 9, wherein the fluid supply element is a elastomeric bulb to be inflated with said fluid, and the sleeve is of a material which is more impervious to said fluid than is the elastomeric material of said bulb (21) thereby to have the effect of slowing the rate of loss of fluid radially outwardly from the bulb (21) through the wall thickness of the bulb.

Claim 11 (withdrawn): A device as claimed in claim 10 wherein the control device (25) comprises a plug which blocks the second lumen at its proximal end and includes a parting line, which enables the plug to be parted into two separate parts, by manual manipulation from outside the lumen, such parting having the effect of opening up fluid communication along the lumen from the elastomeric bulb (21) to the fluid acceptor (20) to fully fill the acceptor.

Claim 12 (withdrawn): Device as claimed in claim 9 wherein the acceptor (20) is made of elastomer.

Claim 13 (withdrawn): Device as claimed in claim 9 and made of latex rubber.

Claim 14 (withdrawn): Device as claimed in claim 9 wherein the fluid is a liquid, and the fluid supply element (21) contains said fluid.

Claim 15 (withdrawn): Device as claimed in claim 14 wherein the fluid is water.

Claim 16 (previously presented): Device as claimed in claim 1, wherein the diameter of the annular part of the plug is at least three times that of the stem.

Claim 17 (original): Device as claimed in claim 16 wherein the annular part comprises an annulus (26) of material with a proximal end face (30) and a distal end face (28) and a bore (29) extending between the two end faces.

Claim 18 (currently amended): Device as claimed in claim either one of claims 16 or 17, wherein said stem (27) extends proximal of the annular port, coaxially therewith and has an outside diameter substantially less than that of said annular port (26).

Claim 19 (original): Device as claimed in claim 18 wherein the stem is friction fitted within the bore (29) of the annular part.

Claim 20 (original): Device as claimed in claim 18 wherein the stem (27) is integral with the annular part and joined to it by a circle of weakness (31).

Claim 21 (original): Device as claimed in claim 20 wherein the annular part and stem are together formed as only one piece of molded polymer material.

Claim 22 (currently amended): Device as claimed in claim 16, wherein the axial length of the annular part of the plug is greater than its largest diameter.

Claim 23. (previously presented): Device as claimed in either one of claims 1 or 16, wherein the length of the cylindrical portion is smaller than its radius.

Claim 24 (previously presented): Device as claimed in either one of claims 1 or 16, in which the tapering portion comprises a frusto-conical or substantially frusto-

Ser. No. 09/720,309
Amdt. dated August 27, 2003
Reply to Office action of March 28, 2003

conical portion which has a small end which is larger than the small end of the tapering portion.

Claim 25 (cancelled):

Claim 26 (previously presented): Device as claimed in claim 24 wherein the tapering portion comprises first and second frusto-conical or substantially frusto-conical portions, of different cone angle, such that the diameter of the tapering portion varies along the axis at a greater rate near the small end of the tapering portion than at the large end of the tapering portion.

Claim 27 (previously presented): Device as claimed in claim 1 in which the stem is cylindrical.

Claim 28 (previously presented): Device as claimed in claim 1 wherein the fluid supply element (21) has an open proximal end (22) closed by a filler valve (24).

Claim 29 (previously presented): Device as claimed in claim 1 and which is a urinary drainage catheter.

Claim 30 (cancelled).

Claim 31 (cancelled).

Claim 32 (cancelled).

Claim 33 (cancelled).

Ser. No. 09/720,309
Amdt. dated August 27, 2003
Reply to Office action of March 28, 2003

Claim 34 (withdrawn): Apparatus as claimed in claim 9 wherein the sleeve is of shrink-wrap material.

Claim 35 (previously presented): Apparatus as claim in claim 1 wherein the elastomeric bulb is sleeved in shrink-wrap material.

Claim 36 (previously presented): Apparatus as claimed in either one of claims 34 or 35 wherein the permeability of the sleeve material to diffusion of water therethrough is less than that of latex rubber.

Claim 37 (previously presented): Apparatus as claimed in either one of claims 34 or 35 wherein the shrink-wrap material is polystyrene.

Claim 38 (previously presented): Apparatus as claimed in either one of claims 34 or 35 wherein the shrink-wrap sleeve incorporates a tear strip.

Claim 39 (cancelled).

Claim 40 (cancelled).

Claim 41 (cancelled).

Claim 42 (cancelled).

Claim 43 (cancelled).

Claim 44 (new): Device as claimed in claim 29 wherein the catheter is a Foley catheter.

Ser. No. 09/720,309
Amdt. dated August 27, 2003
Reply to Office action of March 28, 2003

Claim 45 (new): Method of positioning a plug within a lumen of a medical device, the method comprising the steps of:

- i. providing the plug with an annular portion and a stem, co-axial with the annular portion and having a diameter substantially less than that of the annular portion, the annular portion sealing with the lumen wall;
- ii. presenting an open end of the lumen, for receipt of said plug;
- iii. engaging the stem of the plug with an injector rod;
- iv. advancing the injector rod into the lumen open end and along the lumen to the desired position within the lumen.

Claim 46 (new): Apparatus for positioning a stemmed plug within a lumen of a medical device, the apparatus comprising:

- i. expansion fingers to engage and widen the open end of said lumen; and
- ii. an injector rod to engage the stem of the plug and advance the plug into the open end and along the lumen to a desired position within the lumen.